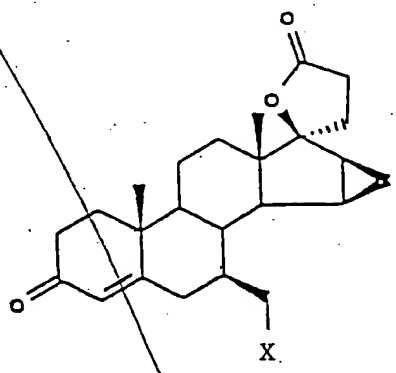
and



wherein X is an anion. --

REMARKS

Claim 5 has been amended to correct an alleged indefiniteness; the scope of the claim is unchanged. Claim 7 was an inadvertent duplicate of claim 6 and has been canceled. New claim 8, a one-step claim, is fully supported in the specification.

New claim 9 is similar to claim 5, except that the second potentially contaminating product recited in claim 9 has an "X" (any anion) in place of the "Cl" recited in claim 5. Support for this recitation is found, *e.g.*, in the specification at page 7, lines 21-23, which indicates that this potentially contaminating product (ring opening product) is obtained when drospirenone decomposes in the presence of any acid (*i.e.*, the general class of acids designated by the formula HX). The specific example of such a decomposition product provided in the specification (ZK 95673 on page 8) is produced by the action of a species of this general class of acids, HCl, and consequently the decomposition product has a Cl at the designated position.

The anticipation rejection is unfounded. The instant claims recite the purity of the claimed drospirenone: a purity of at least 98.9% (claim 4) or in a composition comprising less than 0.2% by weight of the two contaminants recited in claim 5. The reference

(Schulze) does not disclose the purity of its drospirenone. At best, the reference discloses, at col. 8, lines 9-22, that its drospirenone is purified by semipreparative HPLC and that the specific activity is >100 Ci/mmol (420 μg). The Examiner has not pointed to any place in the reference which indicates the degree of purity of drospirenone disclosed therein. To be anticipatory, a reference must disclose all the material elements of a claim (*In re Marshall*, 198 USPQ 344 (CCPA 1967). Schultze does not meet this criterion.

Moreover, in the only portion of the reference which even hints at the degree of purity (col. 8, lines 9-22), Schultze discloses drospirenone which is tritiated. This tritiated compound does not have all of the elements of the instantly claimed compound (*e.g.*, an unlabeled, untritiated H at the position labeled in Schultze). Therefore, for this reason as well, the reference does not anticipate the claimed compound.

In view of the preceding amendments and arguments, the application is believed to be in condition for allowance, which action is respectfully requested.

Respectfully submitted,

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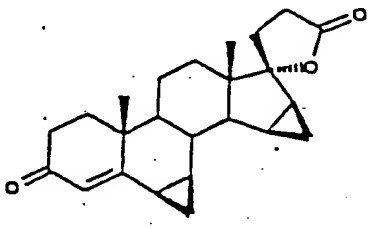
MARKED-UP VERSION

5. (Amended) A ~~preparation~~ composition comprising 6ß, 7ß; 15ß, 16ß-dimethylene-3-oxo-17α-pregn-4-ene-21, 17-carbolactone of claim 4, a pharmaceutically acceptable carrier, ~~comprising~~ and less then 0.2% by weight of said compound of the contaminants



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